K091165

Food and Drug Administration
Device Modification – Horizon XVu- addition of ICECG

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Name:	Mennen Medical Ltd.
Registration Number:	9611022
Operator Number:	9069173
Address:	4 Hayarden Street, Yavne, 81228, Israel
Postal Address:	PO Box 102, Rehovot, 76100, Israel
Tel:	+972-8-9323313
Fax:	+972-8-9328510
Contact person:	Ifat Oren, Regulatory Affairs

Traditional 510(k): Device Modification – Horizon XVu

Terminology

Subject of this 510(k) = Horizon XVu with ICECG
The Horizon XVu is a modified device, a system identical to the Horizon XVu Cathlab with the addition of Intra Cardiac ECG (ICECG) measurement.

This submission is for a modification of the Horizon XVu that Mennen Medical has received 510K clearance for marketing K081484 (see attached FDA approvals in part 21)

We intend to add to the Horizon XVu Computerized Catheterization Laboratory, ICECG measurement option usingas a predicated device the ICECG measurement of the Mennen Medical EMS-XL cardiac electrophysiology system (K071348). (See attached FDA letter Part 21)

Horizon XVu = The predicate device. The Horizon XVu Cathlab was cleared for marketing by the FDA (K081484)

EMS-XL = The predicated device for ICECG measurement. The EMX-XL was cleared for marketing by FDA (K071348)

Intended Use of the Horizon XVu

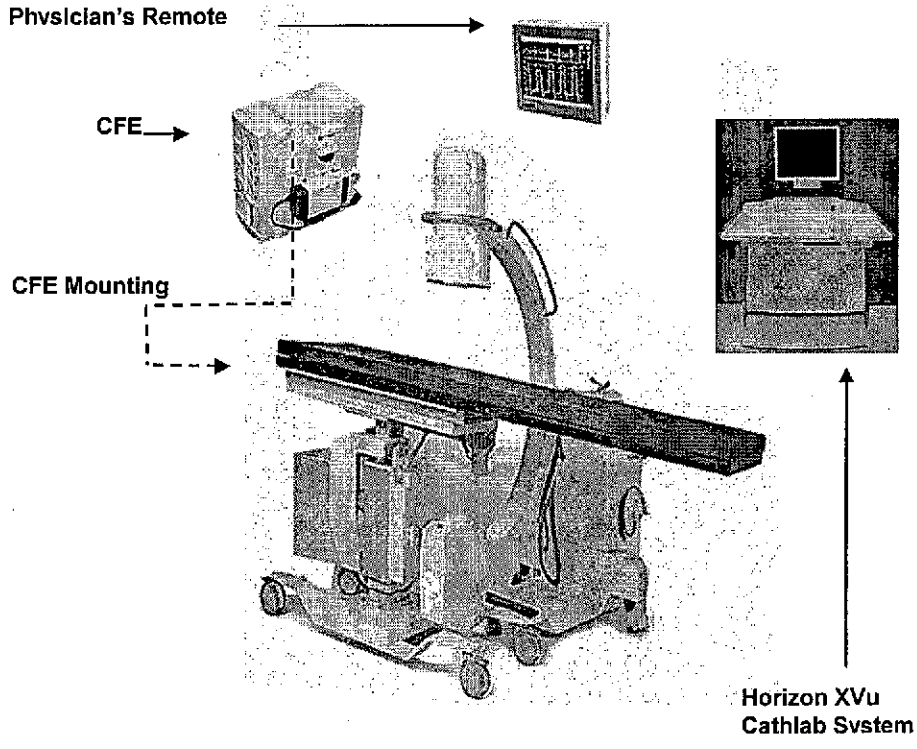
The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, Intra Cardiac ECG (ICECG), invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.

Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

Device Description: Horizon XVu

The prime function of the Horizon XVu (Cathlab) is to acquire and display vital-sign data and waveforms in real time during the catheterization process, creating a fully documented case history.

Horizon XVu System (Console option) – General View



Functional Description of the Horizon XVu

The Horizon XVu is capable of acquiring and displaying essential patientdata such as ECG/Heart Rate, ICECG, invasive blood pressures, pulse oximetry, respiration, cardiac output, and body temperature. Heart rate, multi-lead ECG, EtCO2 and BP waveforms from different heart and vascular sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

The Horizon XVu software includes graphic presentation of the Heart and abdominal, cranial and peripheral vascular system, to support reporting of heart and vascular catheterization.

Catheterization procedure

During a typical catheterization procedure, the physician guides a catheter to the site of interest by observing an X-ray display and the Horizon XVu Patient Data Display, and then instructs the catheterization technician at the on-line workstation to acquire pressure waveform(s) data for that site. With a single keystroke, the technician labels the site and initiates waveform/data sample acquisition.

The waveform of interest changes to a pre-defined color at the Patient Data Display during acquisition for ease of identification. Another keystroke signals the Horizon XVu to stop the acquisition and begin analysis of the newly acquired pressure information via the dedicated Workstation Horizon XVu Computer, at which time the waveform for the corresponding pressure channel will change back to one of the default colors for non-defined pressures.

The Patient Data Procedure Display provides a view of the acquired ECG and heartbeats sampled for review, editing, and acceptance via the Horizon XVu Interface. The numerical results of calculations are based on the average of the accepted beats. These results will include such items as (for example) Systolic, Diastolic, and Mean pressure values.
The technician may at this point use the Interface to accept the displayed pressure information; doing so will store the values to the patient's on-line Procedure File.

The Horizon XVu is used for activities such as coronary and peripheral endovascular procedures and Angioplasty. The basic steps described above (catheter positioning, site definition/acquisition, analysis and acceptance) are performed as an integral part of these procedures.

The system has a computer that utilizes powerful, real-time, software to control the system operation and to process the vital patient sign data measurements acquired from the CFE or entered manually at the keyboard.

A Laser Printer is provided in the system. This provides printouts of textual and graphical summaries of all patient data and catheterization procedures.

Base Configuration: Cathlab parameters

- ECG/Heart Rate/Respiration
- 4 Invasive Blood Pressure channels
- Non-invasive Blood Pressure
- Pulse Oximetry (SpO_2)
- EtCO2 (optional)
- respiration
- temperature
- ICECG – Intra-Cardiac ECG

Horizon SE Options:

- Full Disclosure
- Off-line workstations
- Remote Interactive terminal
- Angiography Analysis Package
- CDR, DVD or Optomagnetic drive
- Choice of Console Table – regular, enhanced, compact or without consol

Main components of the Horizon XVu:
The Horizon XVu system consists of:

(A) a **Front End unit** and
(B) a **Central system**

(A) The **"Cathlab Patient Front End"** (CFE) acquires, processes, and converts vital signs from the patient into digital signals. The CFE then sends the digitized signals and data, via a network connection, to the central system of the Horizon XVu for process and display.

The CFE can acquire the following physiological signals of the patient:

- ECG – the CFE acquires an ECG waveform and measures Heart Rate
- ICECG - the CFE measures 6 channels of differential intra-cardiac ECG
- Blood Pressure – the CFE acquires a BP waveform and measures Systole, Diastole and Mean Pressure
- Temperature – the CFE measures Temperature by means of a numeric value in C° or F°
- SpO_2 – the CFE acquires and measures oxygen saturation and creates a photoplethysmographic waveform and numeric value of the oxygen saturation

- EtCO2 – the CFE measures CO2 during the respiration cycle and present the end tidal (end expiratory) CO2 and the inspired CO2 - inCO2 and the respiration rate - RR

(B) The **Central System** contains the following main devices:

- A SUN® OEM Workstation (computer) – see details on the Sun workstation below
- Two local LCD displays
- Video line driver
- AC Power Unit
- Laser printer
- Hub
- Modem
- Opto-magnetic disk (optional)

ICECG – Intra-Cardiac ECG
Six channels of differential ICECG are incorporated in the CFE – Cathlab front end and displayed on the Horizon XVu.

This enables the user to use an Intra-cardiac electrode catheter and display on the Horizon XVu the ICECG simultaneously with the other vital signs displayed on the Horizon XVu.

The Heart Rate detection is via the surface ECG. The ICECG is capable of showing up to 6 waveforms, and does not have any numeric vital signs.

The addition of an ICECG constitutes a change to the HW technology of the Horizon XVu front end (CFE) and involves an addition of new SW to enable the Horizon XVu to display and control the gain and filters of each channel of the ICECG and to display the ICECG waveforms. In addition the Intended Use were changed accordingly to include the ICECG

ICECG

Mennen Medical has added to the ICECG capability, for the following reasons

- Users request to add to the Horizon XVu the ICECG capability in addition to the hemodynamic analysis.
- ICECG may be useful in arrhythmia analysis

We submit that no changes were made:

- to the control mechanism of the Horizon family products
- to the operating principle of the Horizon family products
- to the energy type of the Horizon family products

As the ICECG option is not sold sterile, sterilization is not an issue.

ICECG capability does not include the catheters, thus sterilization is not an issue.

The advantages of the **Horizon XVu** with 960-OPT-600 on the **Horizon XVu Cathlab** are: Addition of ICECG.

Computer Workstation

The computer workstation is a uni-processor system that runs the Horizon XVu program on a UNIX operating system. The workstation receives the digitized signals from the CFE via the Ethernet hub, displays real-time vital signs, analyzes, processes, and calculates the vital sign data and waveforms, cardiac status in real time during the catheterization process, creating a fully documented case history. The workstation continuously displays the vital signs waveforms and data on the local LCD displays.

The hemodynamic data, ECG and ICECG waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

Description of the design of the Horizon XVu

The Horizon XVu with 960-OPT-600 uses the same hardware and software platform as the Horizon XVu.
The functional menus were modified by adding the option to display the ICECG vital signs and waveform, without any change to the other vital sign monitoring capabilities

1. Substantial Equivalence: Horizon XVu compared to **Horizon with the ICECG option**

Comparison: Horizon XVu ICECG option with Horizon XVu

The following tables summarize and compare data on the Mennen Medical Horizon XVu (predicate device – K081484) to the subject of this 510(k) submittal, the Horizon XVu ICECG

	Horizon XVu	Horizon XVu- ICECG
Part/Option Number	960-800-XXX	960OPT600 ICECG
Input Circuit Parameters		
Surface ECG	Yes	Yes
ICECG	No	Yes

NIBP	**Yes**	**Yes**
Invasive BP	**4 channels**	**same**
Respiration	**Yes**	**Yes**
SpO2	**Yes**	**Yes**
EtCO2	**Yes**	**Yes**

	Mennen Medical Predicated	**Mennen Medical**
	EMS-XL Amplifier	**ICECG (in Horizon XVu)**
Part/Option Number	**960-800-XXX**	**960OPT600 ICECG**
Parameter		
ICECG channels	20/50 Bipolar or Monopolar ICECG	6 Bipolar channels
Patient Isolation	Double isolation Leakage specifications meet or exceed ANSI/AAMI standards.	Same
Common Mode Rejection	100 dB minimum	Same
Input Impedance	2.5 megΩ	Same
IECG – dynamic range	+/- 5 mVolt	Same
IECG – baseline correction	+/- 300 mVolt	Same
IECG – Sampling rate	1000 sample/sec, 16 bit	Same
IECG Bandwidth	500 Hz	Same
Notch filter	50 Hz, 60 Hz, None	Same
Saturation recovery	Less then 1 sec	Same
Gain	0 to 250 continues control	1/4, 1/2, 1, 2, 4, 8
High Pass filter	0.05, 0.2, 40, 80 Hz	0.05, 0.5, 5, 10, 15, 20, 30, 40, 50 Hz
Low Pass filter	500 Hz	200, 250, 300, 350, 400, 450, 500 Hz
Connection	965-030-020 Patient Connection Box	Same

Explanation of differences

The basic amplifier specifications are the same for the EMS-XL (FDA approved) and the Horizon XVu ICECG.

The number of amplifiers is different, since the Horizon XVu is basically a hemodynamic system with limited intracardiac capabilities, while the EMS-XL is intended for full cardiac electro-physiology examinations.

The Horizon XVu has more steps in the HP and LP filters, but the full frequency response of the amplifiers is the same in the two systems.

To summarize the amplifiers of both systems have the same characteristics.

Menu Details

Technician Display

The technician display of the Horizon XVu 960-OPT-600 is identical to the Horizon XVu with the addition of control on the display of the ICECG.

The GUI control keys of the Horizon XVu 960-OPT-600 are similar to the Horizon XVu, with the addition of ICECG.

2. Horizon XVu 960-OPT-600 – **similarity and Differences in Design**:

Horizon XVu with ICECG 960-OPT-600 vs. Horizon XVu

The following technological and other characteristics/features apply to both the Horizon XVu and to the Horizon XVu with 960-OPT-600:

- Intended for use in hospitals
- Do not change the functionality of the Cathlab system
- Isolated inputs for vital signs sensors
- ECG amplifier front end with defibrillator protection
- Invasive BP input circuit
- Non Invasive BP measurement
- SpO2 measurement
- Selectable filters for ECG and BP
- Analog output for ECG and BP
- Doctor's display of vital signs and physiological waveforms
- Show doctor feature for diagrams from the technician screen

The main difference between the Horizon XVu and the Horizon XVu with 960-OPT-600:
On the Horizon XVu with 960-OPT-600 it is possible to display the ICECG waveform

We submit that the addition of the 960-OPT-600 option to the Horizon XVu is limited to the addition of a new parameter - ICECG. This change does not amount to a change in the "fundamental scientific technology" of the Cathlab and does not disqualify the Horizon XVu from being the subject of a 510(k).

The SW changes of the Horizon XVu with 960-OPT-600 vs. the Horizon XVu are not related to the type, size, method of integration, and assembly of the HW components.

The following table compares the major software element and/or changes done in the Horizon XVu vs. the Horizon XVu with 960-OPT-600, Cathlab:

SW Component	**Horizon XVu 960-800-XXX**	**Horizon XVu** with **960OPT600 ICECG**
Doctors display	All waveforms and numeric vital signs	Same
Display of leads and waveforms on Cathlab display screen	Yes	Yes
Solaris Operating System for Cathlab	Yes	Yes
Technician Screen	Controls only	Same
GUI	Same	Same
Menus	Full set	Same
Vital Signs	Full set	Full set + ICECG

3. Conclusion of comparison of technological characteristics:

We consider the ICECG option of the Horizon XVu to be substantially Equivalent to the ICECG in the EMS-XL

We submit that any difference between the ICECG measurement of the Horizon XVu and the ICECG measurement of the EMS-XL.

- fall within the scope of a 510(k) Device Modification and
- do not raise any new issues of safety and effectiveness

4. Verification, Validation and Testing

The Horizon XVu has been subject to extensive performance testing to ensure that:
1. The acquisition and display of the patient data and waveforms by the **Horizon XVu** with 960-OPT-600 remain the same for the predicate device Horizon XVu.

At the system level, SW Validation of the performance of the Horizon XVu with 960-OPT-600 as compared to the Horizon XVu Cathlab system, was carried out in accordance with the test plan described in the Mennen Medical Validation Test Procedure for the Horizon XVu.

The SW Test Description for the Horizon XVu with 960-OPT-600 was derived from the SW Test Description for the Horizon XVu Cathlab system, with the necessary addition of the ICECG measurements

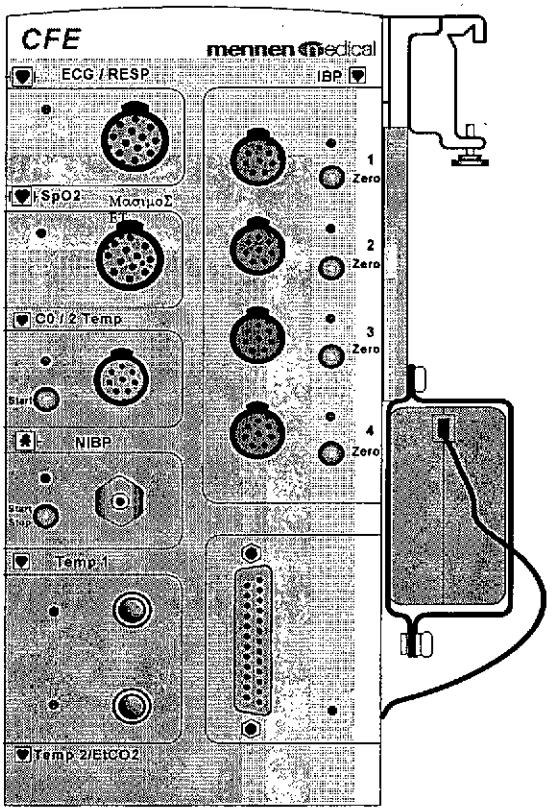
Final testing for the Horizon XVu system included performance tests designed to ensure that the device meets all functional requirements and performance specifications, in accordance with the requirements of the Final Test Procedure for the Horizon XVu system.
Electrical Safety testing and EMC testing were performed by an independent testing laboratory (Standard Institute of Israel SII) to ensure that the device complies to applicable industry and safety standards (attached in Part 17)

5. Proposed Labeling

The system will be called **Horizon XVu** with 960-OPT-600

Page IV of the introduction to the Horizon XVu User Guide contains the following **Prescription Notice:** "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only." The following symbols appear on page IX of the Horizon XVu User's Guides under the section entitled "Label Locations & Symbol Descriptions," and on the front panel of the CFE. See the image of the front panel of the CFE on page 15 below.

	"Attention – see Accompanying Instructions for Use"
	Type BF Applied part (next to NIBP, EtCO2 and SpO_2 connectors)
	Type CF Applied Part (next to IBP, Temperature and CO connectors)
	Type CF Applied Part – Defibrillation Proof (next to ECG connector)



Symbols and labeling on the front panel of the CFE

6. Voluntary Standards

Appropriate voluntary standards for this device, to which conformance have been demonstrated:

- **IEC 60601-1:** (2005) Medical Electrical Equipment Part:1 General Requirements for Safety
- **IEC 60601-1-1** (2000) Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
- **IEC 60601-1-2** (2007): Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- **IEC 60601-2-27** (2005):
  Medical electrical equipment, Part 2,
  Requirements for safety of electrocardiograph monitoring equipment.

- **IEC 60601-2-30** (1999):
  Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment

- **IEC 60601-2-34** (2005):
  Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment

- **IEC 60601-2-49** (2006):
  Particular Requirements for the safety of multifunction patient monitoring equipment

7. Indications for Use

The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, Intra Cardiac ECG (ICECG), invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.

Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 07 2009

Mennen Medical Ltd.
c/o Prof. Yona Mahler
Chief Scientist
4 Ha-Yarden Street
POB 102 Rehovot
Yavne 76100
ISRAEL

Re: K091165
Trade/Device Name: Horizon XVu
Regulatory Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (Two)
Product Code: DQK
Dated: July 7, 2009
Received: July 14, 2009

Dear Prof. Mahler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091165

Indications for Use

510(k) Number (if known): K091165

Device Name: **Horizon XVu**

Indications For Use:

The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, Intra Cardiac ECG (ICECG), invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.

Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

*The Intended Use of the Horizon XVu as indicated above is same as the Indications For Use.

Prescription Use _YES_ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091165